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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/130,213	08/06/98	DEES	H PHO-102

EXAMINER	
RAM, J	
ART UNIT	**PAPER NUMBER**
3739	5

QM22/0508

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DATE MAILED: 05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/130,213	DEES ET AL.	
	Examiner	Art Unit	
	Jocelyn D Ram	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 1998* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-110* is/are pending in the application.

4a) Of the above claim(s) *78-96 and 108-110* is/are withdrawn from consideration.

5)☒ Claim(s) *75-77* is/are allowed.

6)☒ Claim(s) *1-11,13-15,19-29,31-33,37-51 and 55-75* is/are rejected.

7)☒ Claim(s) *12,16-18,30,34-36,52-54 and 97-107* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2-4* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-77 and 97-107, drawn to a method for treating a tissue containing an endogenous pigment with light to promote simultaneous two-photon photoactivation, classified in class 128, subclass 898.

II. Claims 78-96 and 108-110, drawn to an apparatus comprising a light source and a light delivery apparatus, classified in class 607, subclass 89.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used for any type of laser surgery, for example cataract surgery.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Murphy on February 29, 2000 a provisional election was made with traverse to prosecute the invention of the method, claims 1-77 and 97-107. Affirmation of this election must be made by applicant in replying to this Office action. Claims 78-96 and 108-110 are withdrawn from further

consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13-15, 19-29, 31-33, and 37-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 10-15, 17, 19, 20, 29-34, 40-45, 52-55, 60 and 62-67 of U.S. Patent No. 5,829,448. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the instant invention is encompassed by the patented invention. A "photoactive molecular agent" includes "an endogenous pigment".

Claims 1-6 and 19-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 10, 13, 14, 17-20 and 23 of U.S. Patent No. 5,998,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is encompassed by the patented invention. A "photoactive molecular agent" includes "an endogenous pigment".

Claims 37-42, 45-52 and 54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 73-75, 82-84, 89, 90, 92, 99, 85-87 and 79, respectively of copending Application No. 09/096832. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "two-photon excitation" is encompassed by the "multi-photon excitation".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 55-69 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Daikuzono et al. (5,050,597). Daikuzono et al. show a method for treating a volume of tissue comprising the steps of: treating the volume of tissue with light to promote thermal overload of pigmented cells in the tissue, wherein said thermal overload kills said cells (col 3, lines 67-8; col 4, lines 1-16). Although Daikuzono et al. do not explicitly state that the tissue contains an endogenous pigment, there is no disclosure of any photochemical being injected and a photochemical reaction does occur, therefore it can be assumed that this reaction occurs in cells which contain endogenous pigment. The light is produced by a laser that has a pulse duration of about 10 ns and a wavelength of 532 nm, and the tissue is below the tissue surface (Fig. 6). It would have been obvious for one of ordinary skill in the art at the time of the invention to modify the wavelength and the pulse duration to excite a specific photochemical reaction depending on the chemical present in the tissue, and to modify the length of the probe to reach the target area of tissue.

Claims 55, 56, 68, 69 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (5,445,608). Chen et al. show a method for treating tissue comprising: treating the tissue with light to promote thermal overload of pigmented cells, wherein said thermal overload kills said pigmented cells (col 3, lines 6-

13). Although Chen et al. does not show an endogenous pigment, it would have been obvious to one of ordinary skill in that art at the time of the invention to use either an exogenous or an endogenous photodynamic chemical for PDT.

Claims 55-75 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Talmore (5,707,401). Talmore shows a method for treating a volume of tissue comprising the steps of: treating the volume of tissue with light to promote thermal overload of pigmented cells in the tissue, wherein said thermal overload kills said cells (col 3, lines 1-32). Talmore utlizes the absorption spectrum of endogenous pigments such as melanin and hemoglobin (Fig. 2). He uses a laser with a wavelength range of 600-750 nm and 1200-1700 nm (col 3, lines 40-47) and a penetration depth of 1-7 mm (col 3, lines 12-17). Although the pulse rate is not specified, it is within the parameters of the device to allow the user to modify these rates (col 5, lines 20-26).

Allowable Subject Matter

Claim 75-77 are allowed.

Claims 12, 16-18, 30, 34-36, 52-54 and 97-107 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-36 and 97-107 contain allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to show: A method for treatment of a particular volume of tissue, said tissue containing an endogenous pigment, the method comprising the steps of: treating the particular volume of tissue with light to promote a simultaneous two-photon photoactivation of said pigment in the particular volume of tissue, wherein the pigment becomes photochemically activated in the particular volume of tissue. Specifically, the simultaneous two-photon activation, in conjunction with the other elements of the claims is novel.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Daikuzono (5,193,526; 5,209,748), Kawai et al. (4,822,335), Chen et al. (5,571,152; 5,957960), Tan (5,217,455), Kolobanov et al. (4,973,848), Woodburn et al. (5,775,339), Tan (5,290,273; 5,217,455), Hu (5,586,981) all show PDT methods.

The examiner regrets that following the telephone restriction of February 2000, this case was misplaced in the office and the action was never sent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jocelyn D Ram whose telephone number is (703) 308-6392. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JR
May 2, 2001

LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700